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PATENT  
ATTORNEY DOCKET: 55320.001041

PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/535,500 Confirmation No.: Unassigned  
Applicant : Anne Mette Buhl HERTZ, et al.  
Filed : May 18, 2005  
Title : METHODS AND KITS FOR DIAGNOSING AND TREATING B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA  
TC/Art Unit : Unassigned  
Examiner: : Unassigned  
  
Docket No. : 55320.001041  
Customer No. : 21967

**MAIL STOP AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants submit attached Form PTO-SB/08A (modified) for consideration and request the references cited therein be made of record by the U.S. Patent and Trademark Office in the above-captioned application.

Applicants respectfully point out that the submission of the listed references in this Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made by Applicants.

For the convenience of the Examiner in considering the cited references, a copy of each of the cited references is enclosed with this communication. In considering the cited references, it may be noted by the Examiner that certain of the references may contain markings, underlinings, and/or other notations. These markings, underlinings, and/or other notations are not to be construed as drawing the Examiner's attention either to selected parts or away from other parts of the cited references. Any such markings were either present on the copies of the cited

references obtained by the associated individuals, or were made thereon during the study of the references by the associated individuals.

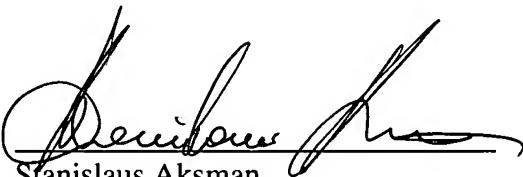
Consideration of the foregoing plus the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is believed to be submitted prior to issuance of a first Office Action. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

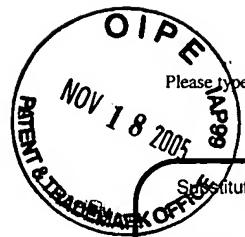
Dated: November 18, 2005 By:



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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*(use as many sheets as necessary)*

Sheet 1 of 4

*Complete if Known*

Application Number	10/535,500
Filing Date	May 18, 2005
First Named Inventor	Anne Mette Buhl HERTZ, et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	55320.001041

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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				Filing Date	May 18, 2005
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				Examiner Name	Unassigned
Sheet	2	of	4	Attorney Docket Number	55320.001041

<b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	7.	Damie et al., "B-Cell Chronic Lymphocytic Leukemia Cells Express a Surface Membrane Phenotype of Activated, Antigen-Experienced B Lymphocytes", Blood, Vol. 99, No. 11, pg. 4087-4090, 2002.		
	8.	Hamblin, "Chronic Lymphocytic Leukaemia: One Disease of Two?", Ann Hematol, Vol. 81, pg. 299-303, 2002.		
	9.	Kröber, et al., "V <sub>H</sub> Mutation Status, CD38 Expression Level, Genomic Aberrations, and Survival in Chronic Lymphocytic Leukemia", Blood, Vol. 100, No. 4, pg. 1410-1416, 2002.		
	10.	Lin et al., "Relationship between p53 Dysfunction, CD38 Expression, and IgV <sub>H</sub> Mutation in Chronic Lymphocytic Leukemia", Blood, Vol. 100, No. 4, pg. 1404-1409, 2002.		
	11.	Jensen et al., "Rapid Tumor Lysis in a Patient with B-Cell Chronic Lymphocytic Leukemia and Lymphocytosis Treated with an Anti-CD20 Monoclonal Antibody (IDE-C2B8, Rituximab)", Ann Hematol, Vol. 77, pg. 89-91, 1998.		
	12.	Muzny et al., "Homosapiens", 12 BAC RP11-693J15, Database EMBL, accession number AC063949, 2000.		
	13.	Andrews et al., "Reconstruction of a Functional Human Type II IL-4/IL-13 Receptor in Mouse B Cells: Demonstration of Species Specificity" J Immunol, Vol. 166, No. 3, pg. 1716-1722, 2001.		
	14.	Bouteiller et al., "Isolation of an IL-13-dependent Subclone of the B9 Cell Line Useful for the Estimation of Human IL-13 Bioactivity", Journal of Immunological Methods, Vol. 181, pg. 29-36, 1995.		
	15.	Chaouchi et al., "Interleukin-13 Inhibits Interleukin-2-Induced Proliferation and Protects Chronic Lymphocytic Leukemia B Cells from In Vitro Apoptosis", Blood, Vol. 87, No. 3, pg. 1022-1029, 1996.		
	16.	Damie et al., "Ig V Gene Mutation Status and CD38 Expression as Novel Prognostic Indicators in Chronic Lymphocytic Leukemia", Blood, Vol. 94, No. 6, pg. 1840-1847, 1999.		
	17.	Dancescu et al., "Interleukin 4 Protects Chronic Lymphocytic Leukemic B Cells from Death by Apoptosis and Upregulates Bcl-2 Expression" J. Exp. Med., Vol. 176, pg. 1319-1326, 1992.		

Examiner Signature	Date Considered
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	18.	Dohner et al., "Genomic Aberrations and Survival in Chronic Lymphocytic Leukemia", The New England Journal of Medicine, Vol. 343, No. 26, pg. 1910-1916, 2000.		
	19.	Fluckiger et al., "IL-13 has only a subset of IL-4-like Activities on B Chronic Lymphocytic Leukaemia Cells", Immunology, Vol. 83, No. 3, pg. 397-403, 1994.		
	20.	Hamblin, et al., "Unmutated Ig V <sub>H</sub> Genes are Associated with a More Aggressive Form of Chronic Lymphocytic Leukemia", Blood, Vol. 94, No. 6, pg. 1848-1854, 1999.		
	21.	Jorgensen et al., Differential Display Competitive Polymerase Chain Reaction: An Optimal Tool for Assaying Gene Expression", Electrophoresis, Vol. 20, pg. 230-240, 1999.		
	22.	Kirn et al., "The Emerging Fields of Suicide Gene Therapy and Virotherapy", Trends in Molecular Medicine, Vol. 8, No. 4, pg. S68-S73, 2002.		
	23.	Kröber et al., "V <sub>H</sub> Mutation Status, CD38 Expression Level, Genomic Aberrations, and Survival in Chronic Lymphocytic Leukemia", Blood, Vol. 100, No. 4, pg. 1410-1416, 2002.		
	24.	Kyte et al., "A Simple Method for Displaying the Hydropathic Character of a Protein", Journal of Molecular Biology, Vol. 157, pg. 105-132, 1982.		
	25.	Liang et al., "Differential Display of Eukaryotic Messenger RNA by Means of the Polymerase Chain Reaction", Science, Vol. 257, pg. 967-971, 1992.		
	26.	Lundin et al., "Interleukin 4 Therapy for Patients with Chronic Lymphocytic Leukaemia: a phase I/II Study", British Journal of Haematology, Vol. 112, pg. 155-160, 2001.		
	27.	Luo et al., Antiproliferative Effect of Interleukin-4 in B Chronic Lymphocytic Leukemia", Journal of Immunotherapy, Vol. 10, pg. 418-425, 1991.		
	28.	Merrifield, "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", J. Am. Chem. Soc., Vol. 85, pg. 2149-2154, 1963.		

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	29.	Panayiotidis et al., "Interleukin-4 Inhibits Apoptotic Cell Death and Loss of the bcl-2 Protein in B-Chronic Lymphocytic Leukaemia Cells <i>in vitro</i> ", British Journal of Haematology, Vol. 85, pg. 439-445, 1993.		
	30.	Petersen et al., "Optimisation of the CT.h4S Bioassay for Detection of Human Interleukin-4 Secreted by Mononuclear Cells Stimulated by Phytohaemagglutinin or by Human Leukocyte Antigen Mismatched Mixed Lymphocyte Culture", Immunology Letters, Vol. 84, pg. 29-39, 2002.		
	31.	Yazawa et al., "Current Progress in Suicide Gene Therapy for Cancer", World J. Surg., Vol. 26, No. 7, pg. 783-789, 2002.		
	32.	Oscier et al., Multivariate Analysis of Prognostic Factors in CLL: Clinical Stage, <i>IGVH</i> gene mutational status, and Loss or Mutation of the <i>p53</i> gene are Independent Prognostic Factors", Blood, Vol. 100, No. 4, pg. 1177-1184, 2002.		
	33.	Standard Search Report in DK2002 01792, dated July 22, 2003.		
	34.	International Search Report in PCT/DK03/00794, dated Augst 16, 2004.		

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